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ance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: SUSTAINED RELEASE TABLET CONTAINING INDAPAMIDE

(57) Abstract: The present invention relates to a sustained release tablet containing indapamide and the process of manufacturing sustained release tablet containing indapamide. The tablet contains indapamide in the amount of 1.5 to 2.5% of the total mass of the tablet, lactose monohydrate in the amount of 30 to 80% of the total mass of the tablet, copovidone in the amount of 2 to 10% of the total mass of the tablet, hypromellose in the amount of 20 to 65% of the total mass of the tablet and lubricants in the amount of 0.1 to 5% of the total mass of the tablet. The process of manufacturing the sustained release tablet consists in mixing of indapamide with lactose monohydrate and copovidone and then, the mixture is moistened by purified water and the granulation process of it is performed. Next the granulate is dried, cooled, mixed with hypromellose and lubricants and compressed in tableting machine. (4 claims)



Internation Application No PCT/P02/00056

Relevant to claim No.

1-4

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

EP 0 519 820 A (ADIR)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Category °

X

Minimum documentation searched (classification system followed by classification symbols) IPC 7-A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

Citation of document, with indication, where appropriate, of the relevant passages

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE, PASCAL, SCISEARCH, CHEM ABS Data

	23 December 1992 (1992-12-23) cited in the application examples 1-5		
X	DAMIEN, GERARD ET AL: "Galenic development and pharmacokinetic indapamide sustained release 1. CLINICAL PHARMACOKINETICS (1999 37(SUPPL. 1), 13-19, XP009004369 page 14 -page 15; table 1	5 mg"	1–4
A	GB 2 123 293 A (ADIR) 1 February 1984 (1984-02-01) examples		1–4
		-/	
<u> </u>	her documents are listed in the continuation of box C.	Patent family members are listed	
"A" docume consid "E" earlier of filing of "L" docume which citatio "O" docume other of the results of the resu	ent defining the general state of the art which is not dered to be of particular relevance document but published on or after the international	 "T" later document published after the Interior priority date and not in conflict with cited to understand the principle or the invention "X" document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the document of particular relevance; the cannot be considered to involve an indocument is combined with one or ments, such combination being obvious in the art. "&" document member of the same patent 	the application but every underlying the staimed invention be considered to current is taken alone staimed invention ventive step when the one other such docuus to a person skilled
Date of the	actual completion of the international search	Date of mailing of the international se	arch report
2	1 January 2003	31/01/2003	
Name and r	mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2	Authorized officer	
	NL 2280 HV Rijswijk Tel (+31-70) 340-2040, Tx. 31 651 epo nl,	}	

PCT/P: 02/00056

0.40	TO DESCRIPTION OF THE PROPERTY	PCT/P 02/00056
	ation) DOCUMENTS CONSIDER TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 36 02 304 A (SANDOZ AG) 7 August 1986 (1986-08-07) example 11	1-4
Α	EP 1 057 479 A (BIOGLAN IRELAND R & D LTD; ENBALT TRADING LTD (IE)) 6 December 2000 (2000-12-06) example 9	1-4
:		

Form PCT/ISA/210 (continuation of second sheet) (July 1992) .

Internation

Application No

ation on patent family members PCT/P 02/00056 Patent document Publication Patent family Publication member(s) cited in search report date date EP 0519820 Α 23-12-1992 FR 24-12-1992 2677886 A1 AT 131050 T 15-12-1995 AU 651894 B2 04-08-1994 AU 1834392 A 24-12-1992 CA 2071408 A1 19-12-1992 DE 69206495 D1 18-01-1996 DE 69206495 T2 25-07-1996 DK 519820 T3 22-04-1996 EP 0519820 A1 23-12-1992 ES 2083119 T3 01-04-1996 GR 3019017 T3 31-05-1996 HK 56397 A 09-05-1997 IE 921952 A1 30-12-1992 JP 2638389 B2 06-08-1997 JP 5186346 A 27-07-1993 US 5334392 A 02-08-1994 ZA 9204482 A 18-08-1993 GB 2123293 Α 01-02-1984 FR 2529785 A1 13-01-1984 AU 557601 B2 24-12-1986 AU 1670283 A 12-01-1984 BE 897251 A1 09-01-1984 CA 1197191 A1 26-11-1985 CH 655007 A5 27-03-1986 DE 3324785 A1 12-01-1984 IE 55364 B1 29-08-1990 1173729 B 24-06-1987 IT JP 2050084 B 01-11-1990 JP 59027813 A 14-02-1984 LU 84902 A1 22-03-1984 NL 8302435 A 01-02-1984 NZ 204849 A 11-04-1986 OA 7489 A 31-03-1985 SE 8303886 A 10-01-1984 ZA 8304978 A 28-03-1984 DE 3602304 10-01-1992 Α 07-08-1986 AT 393960 B AT 26186 A 15-07-1991 ΑU 5293286 A 14-08-1986 BE 904146 A1 31-07-1986 CH 667388 A5 14-10-1988 DE 3602304 A1 07-08-1986 DK 06-08-1986 52186 A ES 8800597 A1 01-02-1988 FR 2576788 A1 08-08-1986 GB 2173399 A 15-10-1986 GR 860307 A1 27-05-1986 HU 44934 A2 30-05-1988 ΙE 860294 L 05-08-1986 IT 1203737 B 23-02-1989 JP 61183221 A 15-08-1986 LU 86290 A1 02-09-1986 NL 01-09-1986 8600137 A PH 23077 A 10-04-1989 01-03-1986 PT 81953 A ZA 8600850 A 30-09-1987 EP 1057479 06-12-2000 IE

950586 A2

01-11-1995

Α

i stion on patent family members

Internation | Application No PCT/PL 02/00056

Patent document cited in search report		Publication date	Patent family member(s)		Publication date	
EP 1057479	Α		EP	1057479 A1	06-12-2000	
			ΑT	199495 T	15-03-2001	
			AU	4353996 A	03-07-1996	
			DE	69520292 D1	12-04-2001	
			DE	69520292 T2	13-06-2001	
			DK	800384 T3	17-04-2001	
			EP	0800384 A1	15-10-1997	
•			ES	2154744 T3	16-04-2001	
			GB	2295966 A ,B	19-06-1996	
			GR	3035863 T3	31-08-2001	
			ΙE	950946 A1	26-06-1996	
			WO	9618386 A1	20-06-1996	
			PT	800384 T	29-06-2001	
			ZA	9510650 A	09-07-1996	